

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MONTANA  
GREAT FALLS DIVISION**

ENVIRONMENTAL DEFENSE FUND;  
MONTANA ENVIRONMENTAL  
INFORMATION CENTER; and CITIZENS  
FOR CLEAN ENERGY,

*Plaintiffs,*

v.

U.S. ENVIRONMENTAL PROTECTION  
AGENCY; and ANDREW R. WHEELER, in  
his official capacity as Administrator of  
the U.S. Environmental Protection  
Agency,

*Defendants.*

Case No.: 4:21-cv-00003-BMM-JTJ

The Honorable Brian Morris,  
Chief Judge

**DECLARATION OF JANE HOPPIN**

I, Jane Hoppin, ScD, declare as follows:

1. My name is Jane Hoppin. I am a professor in the Department of Biological Sciences at North Carolina State University in Raleigh, North Carolina. I am also the Deputy Director of the NC State Center for Human Health and the Environment.

2. I am an environmental epidemiologist whose research focuses on chemicals that are regulated or may be regulated by US Environmental Protection Agency (EPA). I received my doctorate from the Harvard School of Public Health

in 1995 in Environmental Health and Epidemiology. From 1999 to 2013, I was a staff scientist at National Institute of Environmental Health Sciences (NIEHS). Since 2013 I have been on the faculty of North Carolina State University.

3. I am a member of Environmental Defense Fund because I believe in its mission to advocate for science-informed policy and decision making.

4. My research focuses on environmentally exposed populations. I currently have two NIEHS-funded grants focusing on pesticide exposure and health effects in women and children in Costa Rica and on PFAS (per- and polyfluoroalkyl substances) in North Carolina. These studies require me to gather data from study participants including biological samples to measure exposure to chemical contaminants; questionnaires to collect information on medical history and factors that may influence health and disease such as smoking and drinking; clinical measures of height and weight; as well as detailed residential history to characterize potential historic exposure to chemical contaminants.

5. I am aware of the new rule adopted by EPA, known as the “Strengthening Transparency in Pivotal Science Underlying Significant Regulatory Actions and Influential Scientific Information,” which establishes how EPA may consider studies examining “the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and an effect” on human health. *See* 86 Fed. Reg. 469, 470, 492 (Jan. 6, 2021) (codified at 40 C.F.R. § 30.2)

(“Rule”). This Rule would limit EPA’s ability to consider many vital public health studies, and I am very concerned about its impact on my ability to do future research—and on its consequences for the privacy of existing study participants as is guaranteed by our NIH-provided Certificate of Confidentiality.

6. In June 2020, we published the first paper on our project investigating PFAS exposures in the lower Cape Fear River region of North Carolina. This paper describes our work with the GenX Exposure Study, a community-based study designed to investigate PFAS contamination of drinking water as a result of industrial discharge to the Cape Fear River. In this work, we discovered not one, but three, new PFAS chemicals in the blood of almost every resident. For these chemicals, Nafion byproduct<sup>2</sup>, PFO<sub>4</sub>DA, and PFO<sub>5</sub>DoDA, there was no available toxicity information. Toxicity information is critical for decision-makers to evaluate the risk of discharges of specific chemicals to air and water. Without any toxicity information, policy makers and public health officials were unable to assess the potential risk to the almost 250,000 people who were exposed to these chemicals via drinking water, making it impossible to answer community questions regarding how this may impact their health or the health of their children and families. Our research indicates that these chemicals, formed as byproducts of chemical production, are detectable in humans. The discovery of these chemicals is the first step in chemical regulation; knowing they are found in humans means that we need

to evaluate the potential risk of this exposure. The concentrations of chemicals differed among individuals, providing the initial data that may be used to evaluate dose-response with human health effects. To date, we have not published anything on health effects, but discovering exposure, and determining that levels differ among people is the key first step to evaluating the dose-response of chemicals in humans.

7. There is growing concern among public health officials about PFAS chemicals and the need to regulate PFAS releases and PFAS chemicals that are already in the environment. The purpose of my studies is to generate high-quality science that can provide information to communities and regulators for use to inform public policy on these matters. Under the new rule, the results in this paper, and some further dose-response research that builds on them, may not be able to be used by the EPA as pivotal science in its significant regulatory actions and influential scientific information unless I provided full disclosure of the study participants' confidential data. However, the terms of the informed consent form all participants in that study signed prevent me from making all of the data public. Moreover, it is unlikely that people would have been willing to participate in a study if they knew that their information would be disclosed. As noted above, much of the information I collect is highly personal. My ability to promise that participants' confidential information will be kept confidential is a critical element of my ability to recruit participants.

8. It is important to me and my team, and to the study participants, that we be able to use the results of the study to demonstrate to EPA the need to regulate PFAS chemicals. The basis for the GenX Study is to help provide the community with answers about this unique chemical exposure. The fact that there is no regulation of these chemicals is of concern to this community; EPA needs to be able to use all available data from both epidemiologic and laboratory studies to evaluate the potential impact of exposure on human health. My research has made clear that parts of North Carolina are facing a specific risk because the community's exposure to PFAS chemicals is due to a particular source. There is no other place in the world that this exposure is occurring. Accordingly, there is a specific need to address this exposure, and the study provides the scientific basis to begin to analyze how to do that. But if the results of the study—or any future study that relies on or further develops its results—cannot be used by EPA to take regulatory action, much-needed regulatory action would be impossible or delayed.

9. The Rule would impair my future work as well by impacting my ability to conduct scientifically sound research to improve public health policy. I believe the kind of work I do, and plan to do in the future, would be considered “dose-response data” as defined in the Rule. My ability to gain and preserve the trust of study participants, and protect the confidentiality of their personal information, is essential to my work. If study participants knew that their personal information

might need to be shared to support EPA regulatory efforts, they would be less willing to participate in studies. The smaller population who might participate may not be generalizable to the population as whole. Alternatively, participants would not be completely forthcoming with information and that would lead to biased studies.

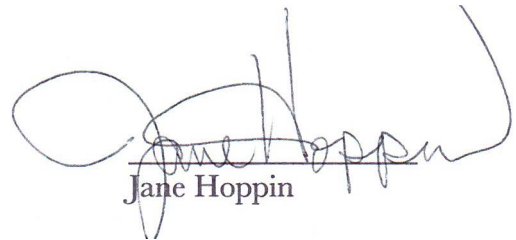
10. The ability of researchers to recruit and retain study participants is key to valid epidemiologic research. The Rule may lead to self-selection of study participants and will make it more difficult to reach communities who have historically been poorly treated by government agencies. The inability to recruit participants will adversely impact researchers in their ability to begin and to continue research projects in impacted communities. PFAS exposure is occurring in diverse communities in North Carolina along the Cape Fear River. These include minority communities within Wilmington, both long-term Black residents as well as recent Hispanic immigrants. And the exposure is not just an urban issue, as private wells in the region around the plant have been impacted and contamination has been detected in Robeson County, which is primarily inhabited by Native American communities. Individuals in many of these groups are historically wary of the government, so any rule that would require sharing personal information with the government would put a damper on study participation.

11. Under the Rule, my research may not be given due weight as EPA develops new public health measures to address the health risks of chemicals and

pollutants. I strongly believe that the Rule will lead to less effective public health policy and EPA decision making because the Rule will deprive EPA of the use of the soundest and most pertinent scientific research on the health effects of chemicals and pollutants.

I declare under the penalty of perjury that the foregoing is true and correct to the best of my knowledge and belief.

Dated: January 7, 2021



Jane Hoppin